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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,463	05/26/2000	Carl J. Wheeler	VICAL1100-1	2067

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/19/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/580,463	WHEELER, CARL J.
	Examiner	Art Unit
	Richard Schnizer	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 47-94 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) 47-94 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .      6) Other: \_\_\_\_.

Art Unit: 1632

### **DETAILED ACTION**

An amendment was received and entered as Paper No. 8 on 1/22/02. Claims 1-46 were canceled and claims 47-94 were added as requested.

Applicant's election with traverse of group I is acknowledged. Applicant's arguments are persuasive in part, and unpersuasive in part. With respect to the issue of restricting methods of delivering agents to plant cells and methods of delivering agents to animal cells, Applicant's arguments are unpersuasive. Applicant argues that restriction is improper because both inventions are recited within a single claim, and relies for support on *In re Weber* and *In re Haas*. These two decisions support the idea that the Office may not restrict between subject matter having unity of invention. In the instant situation, unity of invention is lacking for the reasons given below, *i.e.* the two methods require different reagents and method steps, are not disclosed as being capable of use together, and can be classified independently.

After consideration of Applicant's arguments and suggestions, the previous restriction requirement is withdrawn in view of the following restriction requirement.

Art Unit: 1632

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.     Claims 47-94, drawn to compositions comprising a cationic lipid, and methods of delivering a biologically active agent to an animal cell classified in class 435 subclass 458.
- II.    Claims 47-78 and 82-94, drawn to compositions comprising a cationic lipid and a method of delivering a biologically active agent to a plant cell, classified in class 435, subclass 468.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose how plant and animal cells can be used together in one method. Further, the two methods must have different modes of operation due to the structural differences between plant and animal cells. For example, plant cells comprise a polysaccharide cell wall which is absent from animal cells. This structural difference would require a different mode of operation in order to successfully deliver an agent to

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent

Art Unit: 1632

subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of "R9": C1-C10 substituted alkyl; C1-C10 alkyloxy and polyalkyloxy; C1-C10 substituted alkyloxy and substituted polyalkyloxy; C1-C10 alkenyl; C1-C10 substituted alkenyl; C1-C10 alkenoxy; C1-C10 substituted alkenoxy; NR10-C(O)-NR11; NR12-C(O)-NR13-R16-NR14-C(O)-NR15; C-(O)-NR17, an amino acid, a saccharide, a polysaccharide, a peptidomimetic moiety; a peptide, and a polyamine.

Should Applicant elect the species of polyamine, a further election among the species of peptide, polypeptide, spermine, and spermidine will be required.

Should Applicant then elect the species of polypeptide, a further election among the species of histone, immunoglobulins, transferrin, asialoglycoproteins, integrins, selectins, hormones, major histocompatibility proteins, lysosomotrophic proteins, bacterial exotoxins, low density lipoprotein, alpha-2-macroglobulin will be required.

Should applicant elect hormones, a further election among the species of cytokines, growth hormones and angiotensin will be required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Art Unit: 1632

Several disclosed species were omitted from this requirement. In general, where Applicant disclosed both a genus and species from that genus, election of the species rather than the genus is required. For example, “moiety with DNA binding affinity” was omitted from the election requirement because at least one species of molecule with DNA binding moieties is included in the election, i.e. histones. Should Applicant elect “histones”, and should this species be found allowable, Applicant will be entitled to consideration of additional species as noted below.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1632

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.



Richard Schnizer, Ph.D.